UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

DONOR NETWORK WEST,

Plaintiff,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services;

STEPHANIE CARLTON, in her official capacity as Acting Administrator of the Centers for Medicare & Medicaid Services;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

RENOWN HEALTH,

Intervenor.

Case No. 3:25-cv-00140-ART-CSD

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

(ECF No. 15)

Plaintiff Donor Network West ("DNWest"), an organ procurement organization ("OPO"), sues federal Defendants, including the Centers for Medicare & Medicaid Services ("CMS"), a federal agency, for a preliminary injunction or stay of CMS's decision to grant Intervenor Renown Health's (Renown) application to switch OPOs. The Court holds that the public's interest in not risking the loss of donated organs in Intervenor Renown's organ-donation program strongly outweighs DNWest's risk of irreparable reputational and economic harm and any serious questions on the merits.

I. BACKGROUND

The National Organ Transplant Act ("Transplant Act") is a broad federal policy that addresses the backlog of people in need of organ transplants by

encouraging organ donation and distributing donated organs equitably and effectively. The Act carries out these goals by authorizing the federal agencies to "to provide grants and other payments to a national network of non-profit organizations tasked with acquiring, preserving, and transporting donated organs." *Adventist Health Sys./SunBelt, Inc. v. DHHS*, 17 F.4th 793, 796 (8th Cir. 2021). "This is an incredibly complex effort." *Id.*

A. Parties

Defendant Health & Human Services is a federal agency that contains the Centers for Medicare & Medicaid Services ("CMS"), one of the federal agencies that oversees organ donation and transplant programs. (ECF No. 1.) CMS granted the waiver at issue in this case. (ECF No. 1-1.) Defendants Robert F. Kennedy, Jr., and Stephanie Carlton are administrators for the Medicare program, sued in their official capacities for CMS's grant of the waiver.

Plaintiff Donor Network West ("DNWest") is an Organ Procurement Organization ("OPO") that operates in California and Nevada. DNWest is the third largest OPO in the country and has operated as Renown's OPO for almost forty years. (ECF No. 1-3 at 3, 4.) DNWest has performed well at Renown for the last several years and received accolades for increasing the number of organ donations in Renown's hospital system. (*See* ECF Nos. 1-1, 16-1.) In 2023, DNWest received an interim tier 2 performance rating from CMS. (ECF No. 1-1 at 2.)

Intervenor Renown Health ("Renown") is a healthcare organization with three hospitals in Reno, Nevada, at issue in this case. (ECF No. 47-1.) Renown applied for a waiver to switch OPOs in September 2023. (*Id.*)

Nonparty Nevada Donor Network ("NDN") is the OPO with which Renown applied to partner in place of DNWest. In 2023, NDN received a tier 1 performance evaluation from CMS. (ECF No. 1-1 at 2.)

B. How Organ Procurement Organizations Work

OPOs are private, federally funded organizations that coordinate organ donations across the country. *See* 42 U.S.C. § 273; *Adventist Health*, 17 F.4th at 797. OPOs facilitate organ donation, while separate organizations carry out transplants. *Adventist Health*, 17 F.4th at 797.

i. OPOs and Donation Service Areas

Congress saw the value of OPOs having durable relationships with the hospitals and other organizations and volunteers where they operate. *See, e.g.*, 42 U.S.C. § 1320b-8(a)(1)(B)(iv) (recognizing "length of continuity of a hospital's relationship" with an OPO); 42 U.S.C. § 273(b)(1)(H) (OPOs must have board members who represent hospitals and the public residing in their donation service area). To this end, OPOs are granted four-year monopolies for specified donation service areas. 42 CFR § 486.308. Donation service areas are "geographically irregular areas (within and among states)" that can be constructed around non-geographic factors like religion and cultural background. *See Callahan v. DHHS*, 939 F.3d 1251, 1255 (11th Cir. 2019); (Trans.). During an OPO's four-year term, it must serve "a substantial majority of the hospitals and other health care entities" within its donation service area that have facilities for donations. 42 U.S.C. § 273(b)(3). All donor hospitals must have affiliation agreements with the OPO assigned to their donation service area. 42 U.S.C. § 1320b-8(a)(1)(C).

Donor hospitals work exclusively with the OPO that covers their donation service area, and every hospital that conducts organ recovery or transplantation must have an affiliation with this "designated" OPO. 42 U.S.C. § 1320b-8(a)(1)(C). Renown's designated OPO is DNWest. (*See* ECF No. 16-2 (Renown's Affiliation Agreement with DNWest).)

ii. Waivers for Hospitals to Substitute Designated OPO

Although hospitals must normally work with their designated OPO, a hospital can seek a waiver to work with a different OPO if CMS finds that it meets

two statutory requirements. 42 U.S.C. § 1320b-8(a)(2)(A). CMS must determine that:

> (i) the waiver is expected to increase organ donation; and
> (ii) the waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver.

Id. CMS also considers cost effectiveness, improvements in quality, and the length and continuity of a hospital's relationship with an OPO. *Id.* § 1320b-8(a)(2)(B). Neither the statute nor regulations specify how these factors are to be evaluated.

iii. The Tier System for Evaluating OPO Performance

The Transplant Act requires CMS to evaluate OPO performance every four years. 42 U.S.C. § 273(b)(1)(D)(ii)(I). If OPOs do not meet CMS's performance standards, they are decertified, and their service area becomes open for competitive bidding by other OPOs. *Id.*; *see* 42 C.F.R. § 486.316(b).

In 2020, CMS passed a final rule for evaluating OPOs by comparing statistics among several metrics and separating them into three tiers based on performance compared to all other OPOs. 42 C.F.R. § 486.316. At the end of the four-year certification cycle, tier 1 OPOs retain their service areas, while tier 2 OPOs must compete for their service areas, and tier 3 OPOs are decertified. *Id.* The first recertification period to use the tier system will be in 2026, and it will only consider the tier rating from 2024. *See* 85 Fed. Reg. 77,898, 77,916. CMS shares "preliminary results [tier rating statistics] with each OPO to provide the opportunity to review the information and raise any concerns prior to the results being made publicly available and taking any enforcement action." *Id.* at 77,912. CMS extensively considered the metrics that go into tier ratings, including organ donation rate, transplant rate, and donor potential adjusted for hospitals with waivers. *Id.* at 77, 921–22; *see also* 84 Fed. Reg. 76,228, 7630 *et seq.* (explanation

of factors that go into tier rating).

According to DNWest, the tier system is only meant to evaluate OPO performance across entire service areas over a four-year period, and it arbitrarily fluctuates between interim years. (ECF No. 1 at 11.)

C. Renown Seeks to End Contract with DNWest

Renown's Affiliation Agreement with DNWest requires it to obtain a waiver from CMS to switch OPOs, as required by the statute. (ECF No. 16-2.) In 2023, Renown sent CMS a waiver request to switch OPOs from DNWest to NDN and alerted DNWest of its intent. (ECF No. 1-6.) DNWest alleges that Renown applied for a waiver to switch OPOs in exchange for NDN providing funding for a new transplant center at Renown, and that such an agreement may violate state and federal anti-kickback laws. (*See* ECF No. 1 at 21.) DNWest's CEO claims that Renown's CEO told her that this funding was conditioned on applying for a waiver, and he asked if DNWest could match NDN's funding. (*See* ECF No. 16 at 11.) Renown responds that the transplant center collaboration has nothing to do with the waiver request, and that had the waiver request been denied, NDN and DNWest's collaboration on the transplant center would have continued. (ECF No. 16-3; ECF No. 47-1 at 4.) Shortly after Renown applied for the waiver, DNWest issued public statements about the alleged kickback and sued Renown and NDN. (*See e.g.*, ECF No. 47-3.) That lawsuit is also before this Court. *See Donor Network W. v. Nev. Donor Network, Inc.*, No. 3:23-CV-00632-ART-CSD, 2025 WL 326980 (D. Nev. Jan. 29, 2025). DNWest voluntarily dismissed Renown in January 2024. (ECF No. 47-1).

D. CMS Grants Renown's Waiver Request

CMS opened public comment on Renown's request in November 2023. 88 Fed. Reg. 82,375; *id.* at 82,376, 82,381. It received 89 unique comments of 168 total. (ECF No. 1-1 at 1.) DNWest provides a letter from Congress and an internal email from the Department of Health and Human Services suggesting that CMS

lacks the resources, expertise, and procedures to evaluate a hospital's OPO waiver request. (*See* ECF No. 1 at 13.) CMS approved the waiver in December 2024. (*Id.*) In its four-page waiver decision and eight-page internal analysis, CMS summarized comments and explained its rationale. (ECF No. 1-1; ECF No. 42-3.)

CMS cited two reasons for finding that the waiver would be likely to increase expected organ donation: NDN's higher interim tier rating and DNWest's deteriorating relationship with Renown. CMS considered that the tier system includes organ donation rates, expected transplant rates, observed transplant rates, performance relative to other OPOs based on these rates, and previous assessments on these factors for the previous three years. (ECF No. 42-3 at 4 (citing OPO Public Performance Report, 2023 Assessment).) CMS considered advantages to using the tier system including CMS's collection and analysis of data, which lets the agency avoid relying on an OPO or hospital's self-interested framing of data. (*See* ECF No. 42-3 at 5.)

CMS also concluded that Renown's "working relationship with DNWest has recently deteriorated." (ECF No. 1-1 at 4.) CMS considered DNWest's lawsuit against Renown, DNWest's public statements accusing Renown of kickbacks with NDN, and Renown's other statements regarding its relationship with DNWest. (*See id.* at 3; ECF No.42-3 at 9.) CMS's comments about DNWest's "public statements" refers to several letters submitted to the administrative record that mentioned DNWest's lawsuit and accused Renown of taking kickbacks. (*See* ECF No. 1-2 at 6; ECF No. 1-3 at 27.)

Regarding the second statutory factor, CMS also found that the waiver would "assure equitable treatment." (ECF No. 1-1 at 4); 42 U.S.C. § 1320b-8(a)(2)(A)(ii). CMS found that racial minorities had comparable donation and service rates at both DNWest and NDN, and the increased organ donation expected from the waiver would assure equitable treatment for all those in need of a transplant. (ECF No. 42-3 at 6.) CMS also explained that it did not believe

"that granting the waiver will impact the regional distribution of organs in the service areas of either OPO" and "that the national organ allocation policies . . . will help ensure equitable treatment of patients referred for transplants in both service areas." (ECF No. 1-1 at 4.)

E. DNWest's Harms from CMS's Decision

DNWest alleges that CMS's determination harms their reputation and poses economic problems to their operations in northern Nevada.

DNWest alleges that in Nevada it performs better than NDN in several organ donation metrics. DNWest argues that its kidney discard rate and cost effectiveness is better than NDN's. (*See* ECF No. 1-3.) DNWest also provided charts to show how quickly tier data fluctuates. (ECF No. 45.) These charts show that NDN also would have been rated Tier 2 based on data from December 2024. (ECF No. 45-1.) On one of these charts, NDN has a significantly higher organ donation rate than NDN, while DNWest has a marginally higher organ transplantation rate than NDN. (*Id.*)

DNWest's CEO fears that if Renown implements the allegedly legally defective waiver, it will damage DNWest's reputation, goodwill, and recruiting efforts with hospitals and contractors at Renown and elsewhere in northern Nevada. (ECF No. 16-1 at 7–8.) DNWest's CEO also references harm in "the broader Reno community" and comments from undisclosed "community partners" who have already lowered their opinion DNWest or considered withdrawing from partnerships because of the waiver decision. (*Id.*)

DNWest predicts that losing its staff and revenue stream at Renown would force it to scale down its operations with other northern Nevada hospitals and collaborators, which had been economically feasible because of economies of scale at Renown, ultimately resulting in fewer programs, less goodwill, and less revenue. (*Id.* at 8.) Representations made in the hearing confirmed that DNWest's three coordinators who worked at Renown had already stopped working at

Renown by the time of the hearing. (Trans.)

F. Renown Prepares to Switch OPOs

Following CMS's approval of its request, in December 2024, Renown alerted DNWest that the waiver would take effect on March 31, 2025. (ECF No. 47-2.) DNWest's CEO acknowledged this and told Renown that it would continue providing services until termination. (*Id.*) DNWest filed its lawsuit on March 7, 2025, and notified Renown's CEO of its intent to file a preliminary injunction the same day. (ECF Nos. 1, 45-3.)

Between notifying DNWest and learning of the lawsuit, Renown engaged in "significant planning, instruction, and communications with medical staff." (ECF No. 47-1 at 5.) A practicing nephrologist involved in Renown's organ donation program wrote in a sworn statement that any delay in "would cause considerable disruption to the organ donation operations at Renown and risk the loss of critical organs." (*Id.*)

II. STANDARD OF REVIEW

A preliminary injunction is an "extraordinary" and "drastic" remedy that requires the moving party to clearly show that they carry the burden of persuasion. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (cleaned up). A movant seeking preliminary injunctive relief must show that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). In cases against the government, the last two factors merge into one. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir.), *as amended* (Jan. 14, 2014).

While *Winter* requires a plaintiff to show likelihood of irreparable harm, the Ninth Circuit applies a sliding scale approach to the other factors. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134–35, 1139 (9th Cir. 2011). If the movant

makes a threshold showing of "serious questions going to the merits" instead of likelihood of success on the merits, then strong showings on the remaining factors allow a court to issue the injunction. *See Disney Enterprises, Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (citing *Garcia v. Google Inc.*, 786 F.3d 733, 740 (9th Cir. 2015)). If the movant fails to show serious questions going to the merits, the other factors may not otherwise justify granting the injunction. *Id.*

III. ANALYSIS

The Court considers CMS's argument that DNWest lacks standing, then evaluates whether DNWest is likely to succeed on the merits of any of its APA claims, whether DNWest has shown irreparable injury, and whether the balance of equities and public interest favors granting a preliminary injunction.

A. Standing

Federal Defendants argue that DNWest lacks standing because CMS cannot redress Renown's decision to switch from DNWest to NDN. DNWest responds that the nature of the waiver statute and alleged violation establish standing. To show standing, a party must allege injury in fact traceable to another party's challenged conduct that is likely to be redressed by a favorable judicial decision. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). CMS concedes that DNWest has alleged an injury, but it argues that vacating or staying CMS's waiver decision does not redress the harm of DNWest losing Renown as a hospital partner. (ECF No. 42 at 15–17); *see Hecate Energy LLC v. FERC*, 126 F. 4th 660, 665 (D.C. Cir. 2025) (redressability difficult when relief depends on response of third party's discretion); *see Wash. v. FDA*, 108 F.4th 1163, 1175 (9th Cir. 2024). DNWest responds that the Transplant Act prevents Renown from switching OPOs unless CMS grants it a waiver.

The Court finds that staying or vacating the waiver redresses DNWest's injury. If the waiver is stayed or vacated, Renown may not operate an organ

donation program unless it is partnered with DNWest. *See* 42 U.S.C. § 1320b-8(a)(1)(C). Renown's contract also requires it to continue its partnership with DNWest until agency action allows Renown to exit. (*See* ECF No. 16-2 at 6.)

CMS argues that DNWest's real injury is that Renown wants to end its relationship with DNWest regardless of CMS's waiver decision, and this was the case before CMS issued its decision. *Hunter v. Dep't of Ed.*, 115 F.4th 955, 970 (9th Cir. 2024) (no standing based on injury "that existed prior to a challenged [agency action]").

The Court finds that DNWest's alleged injuries are reputational harm from losing its placement at Renown and needing to scale back operations without revenue generated at Renown. (ECF No. 16-1 at 7.) DNWest is not "equally likely" to suffer these injuries if the waiver is stayed or vacated. *Hunter*, 115 F.4th at 970.

CMS then argues that DNWest's injury is not redressable because Renown could apply for another waiver to switch OPOs that would likely be granted. The "mere fact" that an agency "might again issue a waiver" does not preclude standing under the APA. *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994). The Court finds that DNWest has standing for its APA claims.

B. Preliminary Injunction

1. Likelihood of Success on the Merits

DNWest's claims arise under the Administrative Procedure Act, which allows a court to overturn agency action that is arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, or in excess of statutory authority. 5 U.S.C. § 706(2)(A), (C). An action is arbitrary and capricious if it "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency . . . ." *Bark v. United States Forest Serv.*, 958 F.3d 865, 869 (9th Cir. 2020) (internal citation omitted)).

DNWest argues that CMS's decision was not in accordance with the authority granted CMS by 42 U.S.C. § 1320b-8(a)(2)(A), that CMS failed to address significant comments and objections, and that CMS's decision relied on a clear error of judgment. (ECF No. 16 at 17, 19, 21.)

a. Compliance with the Statute

DNWest argues that CMS exceeded its authority under 42 U.S.C. § 1320b-8(a)(2)(A) by using interim tier ratings for OPOs and DNWest's deteriorating relationship with Renown as bases for its findings. (ECF No. 16 at 17–18.) CMS and Renown respond that these were reasonable factors to consider in its findings granting the waiver application.

Courts "exercise their independent judgment in deciding whether an agency has acted within its statutory authority." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024). In statutory interpretation, analysis begins "with the plain language of the statute." *Cheneau v. Garland*, 997 F.3d 916, 919 (9th Cir. 2021) (citing *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009)). To find the plain language of the statute, courts read the words "in their context and with a view to their place in the overall statutory scheme." *King v. Burwell*, 576 U.S. 473, 486 (2015).

The relevant statute here is the Transplant Act, codified at 42 U.S.C. § 273 *et seq*. A separately codified provision at 42 U.S.C. § 1320b-8(a)(2)(A) requires CMS to grant a waiver to a hospital to switch OPOs if the agency determines:

> (i) the waiver is expected to increase organ donation; and
>
> (ii) the waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver.

i. Expected to Increase Organ Donation

CMS used two bases to determine that letting Renown switch from DNWest to NDN would increase organ donation: NDN's higher tier rating and the breakdown of DNWest's relationship with Renown. The statute permits both of these factors to be used to assess this requirement.

Tier-Rating System Statutory Challenge

DNWest argues that 42 U.S.C. § 1320b-8(a)(2)(A) does not permit CMS to consider tier-ratings when determining if a waiver is expected to increase organ donation. (ECF No. 16 at 18.) CMS responds that CMS may choose how it assesses this question. (ECF No. 42 at 21.)

Neither the statute nor the regulations explicitly provide a methodology to use in deciding whether a waiver is expected to increase organ donation. *See* 42 U.S.C. § 1320b-8(a)(2)(A); 42 C.F.R. § 486.308(e). Read as a whole, the statutory scheme allows the tier system as an acceptable basis for predicting increased organ donation. *See King*, 576 U.S. at 486 (courts construe "statutes, not isolated provisions"). The statute gives CMS authority to develop criteria to gauge the performance of OPOs on "outcome and process performance measures . . . based on empirical evidence . . . of organ donor potential in other related factors in each service area . . . [and] use multiple outcome measures." 42 U.S.C. § 273(b)(1)(a)(D). Under this grant of authority, CMS developed the tier system, which considers multiple outcome measures of organ donor potential, transplant rates, and other factors. *See* 85 Fed. Reg. 77,898 (Dec. 2, 2020); 42 CFR § 486.316. It is not contrary to the statute to use the methodology Congress instructed the agency to develop for assessing OPO performance to assess OPO performance.

DNWest argues that using the tier system to evaluate a single hospital's request for a waiver is contrary to the statute because tiers were designed to compare OPOs across entire donation service areas. (ECF No. 1 at 11, 24.) The

plain reading of the waiver provision, in the context of the statute, does not require CMS to find that organ donation rates will increase at the hospital requesting a waiver. "When the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended." *Cheneau*, 997 F.3d at 920 (internal citation omitted). Other provisions in the Transplant Act require an agency to evaluate "the rate of organ donation" at particular hospitals. *See, e.g.*, 42 U.S.C. §§ 274(f)–2(a)(1), (e). The hospital waiver provision only requires the agency to determine if the waiver is expected to increase organ donation. *See* 42 U.S.C. § 1320b-8(a)(2)(A)(i). CMS did not need to use a hospital-specific methodology to evaluate this factor.

DNWest argues that using the tier system is a bad proxy because it does not account for the treatment of patients in both service areas, ensure effective coverage of service areas, or predict "an increase in donation rates at the particular hospital requesting a waiver." (ECF No. 16 at 18.) The plain reading of the provision and the statute does not require findings on the treatment of patients or "effective coverage" of service areas.

Using Tier Rating to Evaluate Renown's Request was not Arbitrary and Capricious

DNWest further argues that the data considered in the tier system is an inadequate proxy for expected increased organ donation because it measures OPO performance across entire service areas over a four-year period and fluctuates between interim years. (ECF No. 16 at 18; ECF No. 44 at 11–12). This is a challenge to a policy decision, not statutory interpretation. Under deferential arbitrary and capricious review, the Court may not substitute its "policy judgment for that of the agency." *China Unicom (Americas) Operations Ltd. v. FCC*, 124 F.4th 1128, 1151 (9th Cir. 2024) (citing *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). "'[R]eview of an administrative agency's decision begins and ends with the reasoning that the agency relied upon in making that

decision.'" *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013) (quoting *Safe Air for Everyone v. EPA*, 488 F.3d 1088, 1091 (9th Cir. 2007)).

The tier ratings used by CMS to make their decision included relevant data to predicting increased organ donation, like organ donation rates, expected transplant rates, observed transplant rates, performance relative to other OPOs based on these rates, and previous assessments on these factors for the previous three years. (ECF No. 42-3 at 4 (citing OPO Public Performance Report, 2023 Assessment.) CMS also considered other reasonable advantages to the tier system. CMS collects and assembles the data used to evaluate tiers, which avoids the problem of relying on an OPO or hospital's self-interested framing of data, facts noted by CMS. (*See* ECF No. 42-3 at 5 (recognizing this fact from a comment by NDN).) Data from the tier system is made public, which allows OPOs and hospitals to compare relative performance, anticipate possible challenges based on tier performance, or notice and publicize problematic data-collection, data-assembly, or data-reporting practices. The tier system incorporates procedural protections to meet these goals as well. *See also* 85 Fed. Reg. 77,898, 77,912 ("CMS will share preliminary results with each OPO to provide the opportunity to review the information and raise any concerns prior to the results being made publicly available and taking any enforcement action"). Tier data is a reasonable proxy for assessing expected increases in organ donation.

DNWest argues that using tier rating is arbitrary and capricious because ratings fluctuate greatly between years. (*See* ECF No. 45 at 2.) To support this view, DNWest points to data that would have been available to CMS at the time it made its waiver decision in 2024. (*See id.* at 3.) DNWest argues that its own analysis of "Provisional Data" from 2023, showing both NDN and DNWest as tier 2 OPOs, proves that tier ratings change too quickly to accurately gauge waiver requests. (*Id.*; ECF No. 45-1.) While noting that this data still shows NDN as having a higher organ donation rate than DNWest, (ECF No. 45-1 at 2), the Court

lacks a basis for accepting DNWest's assertion that this fluctuation is arbitrary and does not reflect change in performance between years. CMS's adoption of the final rule contemplated performance changes between interim ratings—that is why CMS provides them to OPOs. *See* 85 Fed. Reg. at 77,912. Additionally, the Court is loath to fault CMS for not having used a data set labeled "provisional."

DNWest also argues that basing a waiver request solely on differences in tier rating, without considering factors specific to the applicant hospital and service area, undermines the statutory scheme. DNWest argues that allowing waivers based solely on difference in tier status would incentivize OPOs to raid high-performing hospitals between certification periods. (ECF No. 16 at 18.) DNWest has failed to show that is the case here, because CMS also considered whether either OPO has geographically advantageous locations to serve Renown, cost effectiveness, and the breakdown of Renown and DNWest's relationship. (ECF No. 1-1 at 3–4.)

Renown's Relationship with DNWest

The Transplant Act recognizes that relationships between hospitals and OPOs are relevant to increasing organ donation. The Court construes the statute as a whole and assumes that Congress intended different meanings for "certain language in one part of the statute and different language in another." *See King*, 576 U.S. at 486; *Cheneau*, 997 F.3d at 920. The Transplant Act requires OPOs to "have effective agreements" with hospitals in its service areas, while it only requires that OPOs "have arrangements" with entities like tissue banks. 42 U.S.C. §§ 273(b)(3)(B), (G), (I). The Act funds programs for increasing organ donation rates at particular hospitals that must be "carried out jointly," with joint "leadership responsibility and accountability" by the hospital and OPO. *Id.* §§ 274(f)–2(b), (c). Read together, these provisions show that relationships between OPOs and hospitals are important to the Act's aim of increasing organ donation. CMS found that switching OPOs at Renown would lead to increased organ

donation because Renown's "working relationship with DNWest has recently deteriorated." (ECF No. 1-1 at 4.) Specifically, CMS considered DNWest's lawsuit against Renown, DNWest's public statements accusing Renown of kickbacks with NDN, and Renown's other statements regarding its relationship with DNWest. (*See id.* at 3; ECF No.42-3 at 9.)

DNWest challenges CMS's assessment of the evidence suggesting its relationship with Renown had deteriorated. The Court must uphold the agency's conclusions so long as they are supported by "[m]ore than a scintilla" of evidence. *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013). DNWest argues that the evidence on the administrative record showed that CMS's conclusion that the relationship had soured was based solely on evidence showing a breakdown among senior management. DNWest further argues that failing to recognize this distinction would let a hospital manufacture a waiver for commercial reasons without regard to statutory requirements. (*See* ECF No. 50 at 2.) But here, DNWest's own actions contributed to the relationship's decline.

Sufficient evidence supported CMS's conclusion that DNWest's relationship with Renown deteriorated. CMS concluded that DNWest's "public statements," (*see* ECF No. 1-1 at 3), including several letters submitted to the administrative record showing that DNWest accused Renown of taking kickbacks, led to a breakdown in DNWest's and Renown's relationship. (*See* ECF No. 1-2 at 6; ECF No. 1-3 at 27; *see also* ECF No. 47-3.). The agency reasonably concluded that deteriorating relations could negatively impact organ donation.

ii. Assuring Equitable Treatment

DNWest argues that CMS did not make a reasoned determination that Renown met the second mandatory factor regarding equitable treatment, which provides:

> [T]he waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area

> served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver.

42 U.S.C. § 1320b-8(a)(2)(A)(ii).

CMS's rationale for this determination was based on racial equity, increased expected organ donations with NDN as Renown's OPO, and national policy for allocating transplants. (ECF No. 1-1 at 4–5.) CMS found that racial minorities had comparable donation and service rates at both OPOs, increased organ donation expected from the switch would assure equitable treatment, and that national organ allocation policies will ensure equitable treatment. (ECF No. 42-3 at 6.) CMS also explained that it did not believe "that granting the waiver will impact the regional distribution of organs in the service areas of either OPO" and "that the national organ allocation policies . . . will help ensure equitable treatment of patients referred for transplants in both service areas." (ECF No. 1-1 at 4.)

While DNWest argues that CMS's findings were inadequate, they satisfied the statute. This provision requires equitable allocation of donated organs in the donation service areas of both the existing and replacing OPO. This provision passed into law when an OPO's donation service area could affect where a donated organ would be transplanted. Social Security Act Amendments of 1994, Pub. L. No. 103-432 § 155, 108 Stat 4398, 4438 (1994). Current allocation policies do not allow for donation service areas to be considered in organ allocation decisions. *See Adventist Health*, 17 F.4th at 799–800. DNWest acknowledged this at the hearing. Accordingly, CMS's findings that the waiver would not "impact regional distribution of organs" and that national allocation policies ensure equitable treatment satisfied the statute. (ECF No. 1-1 at 4.)

b. Failure to Respond to Significant Comments

DNWest argues that CMS failed to take into account significant comments that alleged a kickback scheme between Renown and NDN, financial impropriety

at NDN, NDN's poor relationship with its transplant center in Las Vegas, and comments raising policy concerns about rival OPOs to raiding high-performing hospitals. (ECF No. ECF No. 16 at 19–21; ECF No. 44 at 15.)

"An agency must consider and respond to significant comments received during the period for public comment." *Perez v. Mortg. Bankers Ass'in*, 575 U.S. 92, 96 (2015); *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005). Courts may not second-guess an agency's "weighing of risks and benefits" or penalize it "for departing from the . . . inferences and assumptions" of others." *California by & through Becerra v. Azar*, 950 F.3d 1067, 1096 (9th Cir. 2020).

CMS's internal analysis and decision granting the waiver considered the kickback allegations in concluding that DNWest and Renown's relationship had deteriorated. CMS's internal analysis says that DNWest claimed that "Renown Health was offered money by the requested OPO to build a transplant center, and . . . the requested OPO appeared to predicate the gift on Renown Health's application for a waiver." (ECF No. 42-3 at 8–9.) CMS's decision then mentions "Donor Network West's lawsuit against Renown Health and related public statements, which Renown Health contends mischaracterized its intent in seeking to change OPOs." (ECF No. 1-1 at 3.) The agency's mention of the lawsuit refers to DNWest's lawsuit against Renown and NDN alleging a kickback scheme, as confirmed by comments mentioning the lawsuit. (ECF No. 1-3 at 26–27; ECF No. 1-10 at 2.) When read with the internal analysis and comments alleging the kickback, the decision's mention of "related public statements" includes DNWest's allegations of the alleged kickback scheme. (ECF No. 1-1 at 3.) In its concluding paragraph of the "Increased Organ Donation" section, these facts led CMS to conclude that Renown's working relationship with DNWest had deteriorated. (*Id.* at 4.) CMS rejecting DNWest's concern does not make its decision arbitrary and capricious. *See Becerra*, 950 F.3d at 1096.

DNWest also argues that CMS was required to address arguments in the comments that allowing OPOs to bribe high-performing hospitals would undermine the OPO system. (ECF No. 16 at 20–21.) CMS responds that these comments did not relate to the statutory findings it was required to make, and "adverse incentives are a result of the governing statute, which Congress—not CMS—must address." (ECF No. 42 at 25.) Renown also points to regulatory history of the Transplant Act that suggests that CMS had already considered and rejected DNWest's policy concern regarding poaching high-performing hospitals through waivers. (*See* ECF No. 49 (citing 71 Fed. Reg. 30982, 30987 (2006).)

Finally, DNWest argues that CMS failed to consider comments pointing out NDN's allegedly wasteful spending of government funds and NDN's poor relationship with its transplant center in Las Vegas. The internal analysis explicitly mentions and considers these comments in the section labeled "cost effectiveness." (ECF No. 42-3 at 6.) The decision mentions that "organ acquisition costs may be higher if the waiver is granted" and that NDN "has higher organ acquisition costs for kidneys . . . we do not believe that any potential increase would outweigh the other considerations identified." (ECF No. 1-1 at 3, 4.) Though brief, these findings demonstrate that CMS considered these comments, and the Court will not second-guess its weighing. *Becerra*, 950 F.3d at 1096.

c. CMS's Decision in Light of the Evidence Before It

DNWest argues that CMS's decision was unreasonable in light of the evidence considered. (ECF No. 16 at 21–22.) An agency action is arbitrary and capricious if its rationale "runs counter to the evidence" or so implausible that it is not due to a difference in view or the product of agency expertise. *Cal. Energy Comm'n v. Dep't of Energy*, 585 F.3d 1143, 1150–51 (9th Cir. 2009). Courts apply a deferential standard to agency factfinding and policymaking decisions. *Loper Bright*, 603 U.S. at 392.

DNWest's argument here mirrors its first and second claims: CMS did not

properly weigh evidence purporting to show that DNWest is a more effective OPO than NDN, NDN engaged in financial impropriety and kickbacks, and DNWest has a longer relationship with Renown.

Regarding the DNWest's data showing higher performance in Nevada compared to NDN, the Court notes that "where analysis of the relevant documents requires a high level of technical expertise," courts "defer to the informed discretion of the responsible federal agencies." *Arizona ex rel. Darwin v. EPA*, 815 F.3d 519, 530 (9th Cir. 2016) (internal citations and quotations removed). DNWest's statistics showing higher costs and discard rates for some organs over others do not themselves compel the Court to find CMS's use of tier data arbitrary or capricious. *See supra* III.B.1.a.i.II.

Regarding the conflict between DNWest and Renown as an adequate basis for expecting increased organ donation, the Court reiterates the argument made above. *See supra* III.B.1.a.i.III.

CMS also considered the length of DNWest's relationship with Renown, and, as this is not a statutorily required factor for deciding whether to issue a waiver, was not required to weigh it as a factor in its final decision, even though CMS mentioned it. (ECF No. 1-1 at 4.)

Accordingly, the Court holds that the statute does not foreclose using CMS's tier rating and breakdown in a relationship to evaluate the hospital-waiver factors and finds that CMS's consideration of the evidence and comments before it was not arbitrary and capricious. DNWest's claims do not raise serious questions on the merits.

2. Irreparable Harm

DNWest argues it will suffer irreparable reputational harm from the waiver taking effect and irreparable economic harm from scaling down operations in Northern Nevada (ECF No. 16 at 22–25). CMS and Renown respond that DNWest's delay and the speculative nature of its harms do not warrant finding

irreparable reputational harm. (ECF Nos. 42, 47.)

A preliminary injunction requires a showing of likely, not possible, irreparable harm. *Winter*, 555 U.S. at 22. "Intangible injuries" like harm to reputation may qualify as irreparable harm. *Rent-A-Ctr., Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991) (citing *Regents of Univ. of Cal. v. Am. Broadcasting Cos.*, 747 F.2d 511, 519–20 (9th Cir.1984)); *Herb Reed Enters., LLC v. Fla. Ent. Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013) (reversing preliminary injunction for insufficient showing of irreparable harm).

Irreparable reputational damages generally arise when an entity is posed to lose competitively important goodwill at a competitively important time. In *Rent-A-Center*, the plaintiff showed irreparable harm to goodwill when the defendant opened a store five months after having agreed with the plaintiff not to open a store in that location for three years. 944 F.2d at 603. If the plaintiff would have had to wait until the end of litigation to seek damages, it would have been difficult to evaluate the effect of the competitor's presence on prospective consumers. *See id.* Similarly, in *Regents of University of California v. American Broadcasting Companies*, the Ninth Circuit held that the loss of television audience's goodwill from not being able to broadcast a college football game was irreparable. 747 F.2d at 520.

Here, reputational damage from the CMS decision has either already happened or can be addressed by a later decision on the merits. Unlike the prospective consumers in *Rent-A-Center* or the television audiences in *Regents*, DNWest's collaborators—including Renown—have known about Renown's intent to switch OPOs since at least September 2023. (*See* ECF No. 47-1.) DNWest's allegations about the NDN-Renown kickback have been public since at least December 2023. (*See* ECF No. 47-3.) The waiver decision has been public since December 2024. (*See* ECF No. 1-1.) DNWest names "the broader Reno community" and "community partners" who may lower their esteem of DNWest if

the waiver goes into effect, but it has not provided enough explanation about relevant people who are not already familiar with this conflict or who would lose trust in DNWest should they find out about it. *See Titaness Light Shop, LLC v. Sunlight Supply, Inc.*, 585 F. App'x 390, 391 (9th Cir. 2014) (describing absence of a causal chain that alleged reputational harm would likely occur). Reputational harm caused by DNWest employees leaving Renown had already happened by the time of the hearing.

Renown and CMS argue that DNWest's delay in bringing this litigation weighs against finding irreparable harm. DNWest responds that delay is not a dispositive factor. *See Arc of Cal. v. Douglas*, 757 F.3d 975, 990 (9th Cir. 2014); *Cuviello v. City of Vallejo*, 944 F.3d 816, 833 (9th Cir. 2019) (permitting delay over one year for *pro se* plaintiff seeking redress of worsening constitutional violation); *but see Garcia*, 786 F.3d at 746 (three-month delay in filing for injunction reasonable factor to consider in denying injunction). DNWest knew about the waiver for over two months before filing this suit or alerting interested parties of its intent. (*See* ECF Nos. 1, 1-1.) DNWest's delay weighs against finding irreparable harm.

DNWest also argues that allowing the waiver to take effect would require it to "redirect its resources, which may include scaling down its operations" which could in turn "negatively impact its services and hinder its growth trajectory" within its Nevada service area. (ECF No. 16 at 24.) "Where parties cannot typically recover monetary damages flowing from their injury—as is often the case in APA cases—economic harm can be considered irreparable." *E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 677 (9th Cir. 2021). Here, though, DNWest has not identified concrete economic harm beyond relocating three employees who worked inside of Renown. (ECF No. 16-1 at 8.) Under the statute, DNWest is obligated to provide service in its donation service area which still includes northern Nevada. *See* 42 USC § 273(b)(3).

Accordingly, the Court finds that DNWest has shown irreparable harm only in having to relocate three employees, though this limited harm does not outweigh the lack of serious questions on the merits or public interest and equity.

3. Public Interest and Equity

DNWest argues that the public interest and equity favor stopping CMS's allegedly unlawful action, while CMS argues that allowing Renown to receive the waiver it applied for satisfies these factors. (ECF No. 16 at 25; ECF No. 42 at 31.) Renown argues that it has been planning for the switch to NDN for several months and that unexpected judicial intervention could interrupt its organ-donation program. (ECF No. 47 at 18–20.) Renown has the better argument that outweighs all other factors discussed above.

The balance of equities and public interest considerations "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Although there is "no public interest in the perpetuation of unlawful agency action," courts must weigh the "public consequences in employing the extraordinary remedy of injunction." *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016); *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009).

Renown's declaration from a practicing nephrologist involved in the transplant program states that DNWest's last-minute application for injunctive relief would "cause considerable disruption to the organ donation operations at Renown and risk the loss of critical organs." (ECF No. 47-1 at 5; *see also* Trans. (indicating errata to first page of declaration).) Renown and its staff have been planning for a smooth transition from DNWest to NDN for the last several months. (ECF No. 47-1 at 4–5.) While DNWest argues that CMS's decision threatens public trust in organ donation, the Court finds that disruption to the organ-donation system at Renown poses a more serious risk to the public. Renown's credible claim that granting the injunction could risk losing organs outweighs immediate

vindication of DNWest's procedural rights. Additionally, the fact that DNWest could have indicated to CMS and Renown its intent to seek injunctive relief more than two months before it did, (*see* ECF No. 47-2 at 2–3), weighs against granting an injunction. The public interest and balance of equities strongly favors denying the preliminary injunction.

Applying the sliding scale approach to injunctive relief, *All. for the Wild Rockies*, 632 F.3d at 1139, the Court holds that there are not serious questions on the merits and DNWest faces some irreparable harm, but even if serious questions on the merits and irreparable harm exist, the public interest outweighs these factors and requires denying DNWest's motion for a preliminary injunction.

IV. CONCLUSION

The Court denies Plaintiff's motion for preliminary injunctive relief. (ECF No. 15.)

DATED THIS 31st day of March, 2025.

ANNE R. TRAUM
UNITED STATES DISTRICT JUDGE